SEP 2 6 2000

K002793

IV. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter

Company: ESPE Dental AG

Street: ESPE Platz

ZIP-Code, City: D-82229 Seefeld

Federal State: Bavaria

Country: Germany

Establishment Registration Number: 9611385

Contact: Dr. Andreas Petermann
Manager U.S. Regulatory Affairs

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Date of Submission: September 05, 2000

Name of Device

Proprietary Name: Ketac® Cem µ

Classification Name: Dental cement

Common Name: Glass ionomer based dental luting cement

Predicate Device:

Device: Ketac® Cem radiopaque

510(k) Number: K 844846

Description for the Premarket Notification

Ketac® Cem µ is a glass ionomer based dental luting cement for the permanent fixation of dental devices such as crowns and bridges. It is designated according to 21 C.F.R. § 872.3275(b) as a class II device.

ESPE is submitting this Special 510(k) for modifications to its glass ionomer based luting cement Ketac® Cem radiopaque

The modified dental cement Ketac® Cem µ has the following similarities to the un-modified Ketac® Cem radiopaque:

- Ketac® Cem µ has the same intended use.
- Ketac® Cem µ is used by the same operating principle.
- Ketac® Cem µ incorporates the same basic chemical design.
- Ketac® Cem µ is manufactured and packaged using basically the same materials and processes.

Ketac® Cem µ contains ingredients which are not contained in Ketac® Cem radio-paque. However, these components can be found in other 510(k) cleared devices manufactured by ESPE.

The physical and mechanical properties of Ketac® Cem µ have been compared to those of Ketac® Cem radiopaque. The results provide evidence that the modified product is as effective as the well-established cement.

In summary, the modified material Ketac® Cem µ described in this Special 510(k) premarket notification submission is, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2000

Mr. Andreas Petermann
Manager of Unites States Regulatory Affairs
ESPE Dental AG
ESPE Platz
D-82229 Seefeld, Bavaria
GERMANY

Re: K002793
Trade Name: Ketac Cem U
Regulatory Class: II
Product Code: EMA
Dated: September 5, 2000
Received: September 7, 2000

Dear Mr. Petermann:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002793

D. Statement of Indications for Use

Device Name:	Ketac® Cem µ
Indications for Use:	Cementation of inlays, onlays, crowns and bridges Luting cement for use on orthodontic strips Relinings

Susan Runde

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002793